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110TH CONGRESS 2D SESSION

H.R. 6252

To amend part B of title XVIII of the Social Security Act to delay and reform the Medicare competitive acquisition program for purchase of durable medical equipment, prosthetics, orthotics, and supplies.

IN THE HOUSE OF REPRESENTATIVES

June 12, 2008

Mr. Stark (for himself, Mr. Camp of Michigan, Mr. Rangel, Mr. Boehner, Mr. Dingell, Mr. Pallone, Mr. Allen, Mr. Altmire, Ms. Berkley, Mr. Blumenauer, Mrs. Boyda of Kansas, Mr. English of Pennsylvania, Mr. Sam Johnson of Texas, Mrs. Jones of Ohio, Mr. Kildee, Mr. Kind, Mr. Klein of Florida, Mr. Larson of Connecticut, Mr. Lewis of Georgia, Mrs. McCarthy of New York, Mr. McCotter, Mr. McNulty, Mrs. Miller of Michigan, Mr. Porter, Mr. Reynolds, Mr. Ryan of Ohio, Ms. Schwartz, Mr. Thompson of California, and Mr. Walberg) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

- To amend part B of title XVIII of the Social Security Act to delay and reform the Medicare competitive acquisition program for purchase of durable medical equipment, prosthetics, orthotics, and supplies.
 - 1 Be it enacted by the Senate and House of Representa-
 - 2 tives of the United States of America in Congress assembled,

1	SECTION 1. SHORT TITLE.
2	This Act may be cited as the "Medicare DMEPOS
3	Competitive Acquisition Reform Act of 2008".
4	SEC. 2. DELAY IN AND REFORM OF MEDICARE DMEPOS
5	COMPETITIVE ACQUISITION PROGRAM.
6	(a) Temporary Delay and Reform.—
7	(1) IN GENERAL.—Section 1847(a)(1) of the
8	Social Security Act (42 U.S.C. 1395w-3(a)(1)) is
9	amended—
10	(A) in paragraph (1)—
11	(i) in subparagraph (B)(i), in the
12	matter before subclause (I), by inserting
13	"consistent with subparagraph (D)" after
14	"in a manner";
15	(ii) in subparagraph (B)(i)(II), by
16	striking "80" and "in 2009" and inserting
17	"an additional 70" and "in 2011", respec-
18	tively;
19	(iii) in subparagraph (B)(i)(III), by
20	striking "after 2009" and inserting "after
21	2011 (or, in the case of national mail order
22	for items and services, after 2010)"; and
23	(iv) by adding at the end the following
24	new subparagraphs:
25	"(D) Changes in competitive acquisi-
26	TION PROGRAMS.—

1	"(i) ROUND 1 OF COMPETITIVE AC-
2	QUISITION PROGRAM.—Notwithstanding
3	subparagraph (B)(i)(I) and in imple-
4	menting the first round of the competitive
5	acquisition programs under this section—
6	"(I) the contracts awarded under
7	this section before the date of the en-
8	actment of this subparagraph are ter-
9	minated, no payment shall be made
10	under this title on or after the date of
11	the enactment of this subparagraph
12	based on such a contract, and, to the
13	extent that any damages may be ap-
14	plicable as a result of the termination
15	of such contracts, such damages shall
16	be payable from the Federal Supple-
17	mentary Medical Insurance Trust
18	Fund under section 1841;
19	"(II) the Secretary shall conduct
20	the competition for such round in a
21	manner so that it occurs in 2009 with
22	respect to the same items and services
23	and the same areas, except as pro-
24	vided in subclauses (III) and (IV);

"(III) the Secretary shall exclude	1
Puerto Rico so that such round of	2
competition covers 9, instead of 10, of	3
the largest metropolitan statistical	4
areas; and	5
"(IV) there shall be excluded	6
negative pressure wound therapy	7
items and services.	8
Nothing in subclause (I) shall be construed	9
to provide an independent cause of action	10
or right to administrative or judicial review	11
with regard to the termination provided	12
under such subclause.	13
4 "(ii) ROUND 2 OF COMPETITIVE AC-	14
QUISITION PROGRAM.—In implementing	15
the second round of the competitive acqui-	16
sition programs under this section de-	17
scribed in subparagraph (B)(i)(II)—	18
"(I) the metropolitan statistical	19
areas to be included shall be those	20
1 metropolitan statistical areas selected	21
by the Secretary for such round as of	22
June 1, 2008; and	23
"(II) the Secretary may sub-	24
divide metropolitan statistical areas	25

1	with populations (based upon the
2	most recent data from the Census Bu-
3	reau) of at least 8,000,000 into sepa-
4	rate areas for competitive acquisition
5	purposes.
6	"(iii) Exclusion of certain areas
7	IN SUBSEQUENT ROUNDS OF COMPETITIVE
8	ACQUISITION PROGRAMS.—In imple-
9	menting subsequent rounds of the competi-
10	tive acquisition programs under this sec-
11	tion, including under subparagraph
12	(B)(i)(III), for competitions occurring be-
13	fore 2015, the Secretary shall exempt from
14	the competitive acquisition program (other
15	than national mail order) the following:
16	"(I) Rural areas.
17	"(II) Metropolitan statistical
18	areas not selected under round 1 or
19	round 2 with a population of less than
20	250,000.
21	"(III) Areas with a low popu-
22	lation density within a metropolitan
23	statistical area that is otherwise se-
24	lected, as determined for purposes of
25	paragraph (3)(A).

1 3	"(E) VERIFICATION BY OIG.—The Inspec-
2	tor General of the Department of Health and
3	Human Services shall, through post-award
4	audit, survey, or otherwise, assess the process
5	used by the Centers for Medicare & Medicaid
6	Services to conduct competitive bidding and
7	subsequent pricing determinations under this
8	section that are the basis for pivotal bid
9	amounts and single payment amounts for items
10	and services in competitive bidding areas under
11	rounds 1 and 2 of the competitive acquisition
12	programs under this section and may continue
13	to verify such calculations for subsequent
14	rounds of such programs.
15	"(F) Supplier feedback on missing fi-
16	NANCIAL DOCUMENTATION.—
17	"(i) IN GENERAL.—In the case of a
18	bid where one or more covered documents
19	in connection with such bid have been sub-
20	mitted not later than the covered document
21	review date specified in clause (ii), the Sec-
22	retary—
23	"(I) shall provide, by not later
24	than 45 days (in the case of the first
25	round of the competitive acquisition

1	programs as described in subpara-
2	graph (B)(i)(I)) or 90 days (in the
3	case of a subsequent round of such
4	programs) after the covered document
5	review date, for notice to the bidder of
6	all such documents that are missing
7	as of the covered document review
8	date; and
9	"(II) may not reject the bid or
10	the basis that any covered document
11	is missing or has not been submitted
12	on a timely basis, if all such missing
13	documents identified in the notice pro-
14	vided to the bidder under subclause
15	(I) are submitted to the Secretary not
16	later than 10 business days after the
17	date of such notice.
18	"(ii) Covered document review
19	DATE.—The covered document review date
20	specified in this clause with respect to a
21	competitive acquisition program is the
22	later of—
23	"(I) the date that is 30 days be-
24	fore the final date specified by the

1	Secretary for submission of bids
2	under such program; or
3	"(II) the date that is 30 days
4	after the first date specified by the
5	Secretary for submission of bids
6	under such program.
7	"(iii) Limitations of process.—
8	The process provided under this subpara-
9	graph—
10	"(I) applies only to the timely
11	submission of covered documents;
12	"(II) does not apply to any deter-
13	mination as to the accuracy or com-
14	pleteness of covered documents sub-
15	mitted or whether such documents
16	meet applicable requirements;
17	"(III) shall not prevent the Sec-
18	retary from rejecting a bid based on
19	any basis not described in clause
20	(i)(II); and
21	"(IV) shall not be construed as
22	permitting a bidder to change bidding
23	amounts or to make other changes in
24	a bid submission.

1	(IV) COVERED DOCUMENT DE-
2	FINED.—In this subparagraph, the term
3	'covered document' means a financial, tax,
4	or other document required to be sub-
5	mitted by a bidder as part of an original
6	bid submission under a competitive acqui-
7	sition program in order to meet required
8	financial standards. Such term does not in-
9	clude other documents, such as the bid
10	itself or accreditation documentation.";
11	and
12	(B) in paragraph (2)(A), by inserting be-
13	fore the period at the end the following: "and
14	excluding certain complex rehabilitative power
15	wheelchairs recognized by the Secretary as clas-
16	sified within group 3 or higher (and related ac-
17	cessories when furnished in connection with
18	such wheelchairs)".
19	(2) Budget neutral offset.—
20	(A) In General.—Section 1834(a)(14) of
21	such Act (42 U.S.C. 1395m(a)(14)) is amend-
22	ed—
23	(i) by striking "and" at the end of
24	subparagraphs (H) and (I);

1	(ii) by redesignating subparagraph (J)
2	as subparagraph (M); and
3	(iii) by inserting after subparagraph
4	(I) the following new subparagraphs:
5	"(J) for 2009—
6	"(i) in the case of items and services
7	furnished in any geographic area, if such
8	items or services were selected for competi-
9	tive acquisition in any area under the com-
10	petitive acquisition program under section
11	1847(a)(1)(B)(i)(I) before July 1, 2008,
12	including diabetic supplies but only if fur-
13	nished through mail order, - 9.5 percent;
14	or
15	"(ii) in the case of other items and
16	services, the percentage increase in the
17	consumer price index for all urban con-
18	sumers (U.S. urban average) for the 12-
19	month period ending with June 2008;
20	"(K) for 2010, 2011, 2012, and 2013, the
21	percentage increase in the consumer price index
22	for all urban consumers (U.S. urban average)
23	for the 12-month period ending with June of
24	the previous year;
25	"(L) for 2014—

1	"(i) in the case of items and services
2	described in subparagraph (J)(i) for which
3	a payment adjustment has not been made
4	under subsection (a)(1)(F)(ii) in any pre-
5	vious year, the percentage increase in the
6	consumer price index for all urban con-
7	sumers (U.S. urban average) for the 12-
8	month period ending with June 2013, plus
9	2.0 percentage points; or
0	"(ii) in the case of other items and
1	services, the percentage increase in the
2	consumer price index for all urban con-
13	sumers (U.S. urban average) for the 12-
4	month period ending with June 2013;
5	and".
6	(B) Conforming treatment for cer-
7	TAIN ITEMS AND SERVICES.—The second sen-
8	tence of section 1842(s)(1) of such Act (42
9	U.S.C. 1395u(s)(1)) is amended by striking
20	"except that" and all that follows and inserting
21	the following: "except that for items and serv-
22	ices described in paragraph (2)(D)—
23	"(A) for 2009 section 1834(a)(14)(J)(i) shall
24	apply under this paragraph instead of the percent-
25	age increase otherwise applicable: and

1	"(B) for 2014, if subparagraph (A) applied to
2	the items and services and there has not been a pay-
3	ment adjustment under subsection (h)(1)(H) for the
4	items and services for any previous year, the per-
5	centage increase computed under section
6	1834(a)(14)(L)(i) shall apply instead of the percent-
7	age increase otherwise applicable.".
8	(3) Conforming Delay.—Subsections
9	(a)(1)(F) and $(h)(1)(H)$ of section 1834 of the So-
10	cial Security Act (42 U.S.C. 1395m) are each
11	amended by striking "January 1, 2009" and insert-
12	ing "January 1, 2011".
13	(4) Considerations in application.—Sec-
14	tion 1834 of such Act (42 U.S.C. 1395m) is amend-
15	ed—
16	(A) in subsection (a)(1)—
17	(i) in subparagraph (F), by inserting
18	"subject to subparagraph (G)," before
19	"that are included"; and
20	(ii) by adding at the end the following
21	new subparagraph:
22	"(G) Use of information on competi-
23	TIVE BID RATES.—The Secretary shall specify
24	by regulation the methodology to be used in ap-
25	plying the provisions of subparagraph (F)(ii)

1	and subsection (h)(1)(H)(ii). In promulgating
2	such regulation, the Secretary shall consider the
3	costs of items and services in areas in which
4	such provisions would be applied compared to
5	the payment rates for such items and services
6	in competitive acquisition areas."; and
7	(B) in subsection (h)(1)(H), by inserting
8	"subject to subsection (a)(1)(G)," before "that
9	are included".
10	(b) Quality Standards.—
11	(1) Application of accreditation require-
12	MENT.—
13	(A) In general.—Section 1834(a)(20) of
14	the Social Security Act (42 U.S.C.
15	1395m(a)(20)) is amended—
16	(i) in subparagraph (E), by inserting
17	"including subparagraph (F)," after
18	"under this paragraph,"; and
19	(ii) by adding at the end the following
20	new subparagraph:
21	"(F) Application of accreditation re-
22	QUIREMENT.—In implementing quality stand-
23	ards under this paragraph—
24	"(i) subject to clause (ii), the Sec-
25	retary shall require suppliers furnishing

1	items and services described in subpara-
2	graph (D) on or after October 1, 2009, di-
3	rectly or as a subcontractor for another en-
4	tity, to have submitted to the Secretary
5	evidence of accreditation by an accredita-
6	tion organization designated under sub-
7	paragraph (B) as meeting applicable qual-
8	ity standards; and
9	"(ii) in applying such standards and
10	the accreditation requirement of clause (i)
11	with respect to eligible professionals (as
12	defined in section 1848(k)(3)(B)), and in-
13	cluding such other persons, such as
14	orthotists and prosthetists, as specified by
15	the Secretary, furnishing such items and
16	services—
17	"(I) such standards and accredi-
18	tation requirement shall not apply to
19	such professionals and persons unless
20	the Secretary determines that the
21	standards being applied are designed
22	specifically to be applied to such pro-
23	fessionals and persons; and
24	"(II) the Secretary may exempt
25	such professionals and persons from

1	such standards and requirement if the
2	Secretary determines that licensing,
3	accreditation, or other mandatory
4	quality requirements apply to such
5	professionals and persons with respect
6	to the furnishing of such items and
7	services.".
8	(B) Construction.—Section
9	1834(a)(20)(F)(ii) of the Social Security Act,
0	as added by subparagraph (A), shall not be con-
1	strued as preventing the Secretary of Health
2	and Human Services from implementing the
3	first round of competition under section 1847
4	of such Act on a timely basis.
5	(2) Disclosure of Subcontractors under
6	COMPETITIVE ACQUISITION PROGRAM.—Section
7	1847(b)(3) of such Act (42 U.S.C. 1395w-3(b)(3))
8	is amended by adding at the end the following new
9	subparagraph:
20	"(C) DISCLOSURE OF SUBCONTRAC-
21	TORS.—
22	"(i) Initial disclosure.—Not later
23	than 10 days after the date a supplier en-
24	ters into a contract with the Secretary
25	under this section, such supplier shall dis-

1	close to the Secretary, in a form and man-
2	ner specified by the Secretary, the infor-
3	mation on—
4	"(I) each subcontracting relation-
5	ship that such supplier has in fur-
6	nishing items and services under the
7	contract; and
8	"(II) whether each such subcon-
9	tractor meets the requirement of sec-
10	tion 1834(a)(20)(F)(i), if applicable
11	to such subcontractor.
12	"(ii) Subsequent disclosure.—Not
13	later than 10 days after such a supplier
14	subsequently enters into a subcontracting
15	relationship described in clause (i)(II),
16	such supplier shall disclose to the Sec-
17	retary, in such form and manner, the in-
18	formation described in subclauses (I) and
19	(II) of clause (i).".
20	(3) Competitive acquisition ombudsman.—
21	Such section is further amended by adding at the
22	end the following new subsection:
23	"(f) Competitive Acquisition Ombudsman.—The
24	Secretary shall provide for a competitive acquisition om-
25	budsman within the Centers for Medicare & Medicaid

1	Services in order to respond to complaints and inquiries
2	made by suppliers and individuals relating to the applica-
3	tion of the competitive acquisition program under this sec-
4	tion. The ombudsman may be within the office of the
5	Medicare Beneficiary Ombudsman appointed under sec-
6	tion 1808(c). The ombudsman shall submit to Congress
7	an annual report on the activities under this subsection,
8	which report shall be coordinated with the report provided
9	under section 1808(c)(2)(C).".
10	(c) Change in Reports and Deadlines.—
11	(1) GAO REPORT.—Section 302(b)(3) of the
12	Medicare Prescription Drug, Improvement, and
13	Modernization Act of 2003 (Public Law 108–173) is
14	amended—
15	(A) in subparagraph (A)—
16	(i) by inserting "and as amended by
17	section 2 of the Medicare DMEPOS Com-
18	petitive Acquisition Reform Act of 2008"
19	after "as amended by paragraph (1)"; and
20	(ii) by inserting before the period at
21	the end the following: "and the topics spec-
22	ified in subparagraph (C)";
23	(B) in subparagraph (B), by striking "Not
24	later than January 1, 2009," and inserting
25	"Not later than 1 year after the first date that

1	payments are made under section 1847 of the
2	Social Security Act,"; and
3	(C) by adding at the end the following new
4	subparagraph:
5	"(C) Topics.—The topics specified in this
6	subparagraph, for the study under subpara-
7	graph (A) concerning the competitive acquisi-
8	tion program, are the following:
9	"(i) Beneficiary access to items and
10	services under the program, including the
11	impact on such access of awarding con-
12	tracts to bidders that—
13	"(I) did not have a physical pres-
14	ence in an area where they received a
15	contract; or
16	"(II) had no previous experience
17	providing the product category they
18	were contracted to provide.
19	"(ii) Beneficiary satisfaction with the
20	program and cost savings to beneficiaries
21	under the program.
22	"(iii) Costs to suppliers of partici-
23	pating in the program and recommenda-
24	tions about ways to reduce those costs

1	without compromising quality standards or
2	savings to the Medicare program.
3	"(iv) Impact of the program on small
4	business suppliers.
5	"(v) Analysis of the impact on utiliza-
6	tion of different items and services paid
7	within the same Healthcare Common Pro-
8	cedure Coding System (HCPCS) code.
9	"(vi) Costs to the Centers for Medi-
10	care & Medicaid Services, including pay-
11	ments made to contractors, for admin-
12	istering the program compared with ad-
13	ministration of a fee schedule, in compari-
14	son with the relative savings of the pro-
15	gram.
16	"(vii) Impact on access, Medicare
17	spending, and beneficiary spending of any
18	difference in treatment for diabetic testing
19	supplies depending on how such supplies
20	are furnished.
21	"(viii) Such other topics as the Comp-
22	troller General determines to be appro-
23	priate.".
24	(2) Delay in other deadlines.—

1	(A) Program advisory and oversight
2	COMMITTEE.—Section 1847(c)(5) of the Social
3	Security Act (42 U.S.C. 1395w-3(c)(5)) is
4	amended by striking "December 31, 2009" and
5	inserting "December 31, 2011".
6	(B) Secretarial Report.—Section
7	1847(d) of such Act (42 U.S.C. 1395w-3(d)) is
8	amended by striking "July 1, 2009" and insert-
9	ing "July 1, 2011".
10	(C) IG REPORT.—Section 302(e) of the
11	Medicare Prescription Drug, Improvement, and
12	Modernization Act of 2003 (Public Law 108–
13	173) is amended by striking "July 1, 2009"
14	and inserting "July 1, 2011".
15	(3) Evaluation of Certain Code.—The Sec-
16	retary of Health and Human Services shall evaluate
17	the existing Healthcare Common Procedure Coding
18	System (HCPCS) code for negative pressure wound
19	therapy to ensure accurate reporting and billing for
20	items and services under such code. In carrying out
21	such evaluation, the Secretary shall use the existing
22	process for the consideration of coding changes and
23	consider all relevant studies and information fur-
24	nished pursuant to such process.
25	(d) Other Provisions.—

1	(1) Exemption from competitive acquisi-
2	TION FOR CERTAIN OFF-THE-SHELF ORTHOTICS.—
3	Section 1847(a) of the Social Security Act (42
4	U.S.C. 1395w-3(a)) is amended by adding at the
5	end the following new paragraph:
6	"(7) Exemption from competitive acquisi-
7	TION.—The programs under this section shall not
8	apply to the following:
9	"(A) CERTAIN OFF-THE-SHELF
10	ORTHOTICS.—Items and services described in
11	paragraph (2)(C) if furnished—
12	"(i) by a physician or other practi-
13	tioner (as defined by the Secretary) to the
14	physician's or practitioner's own patients
15	as part of the physician's or practitioner's
16	professional service; or
17	"(ii) by a hospital to the hospital's
18	own patients during an admission or on
19	the date of discharge.
20	"(B) CERTAIN DURABLE MEDICAL EQUIP-
21	MENT.—Those items and services described in
22	paragraph (2)(A)—
23	"(i) that are furnished by a hospital
24	to the hospital's own patients during an
25	admission or on the date of discharge; and

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1	"(ii) to which such programs would
2	not apply, as specified by the Secretary, if
3	furnished by a physician to the physician's
4	own patients as part of the physician's
5	professional service.".
6	(2) Correction in face-to-face examina-
7	TION REQUIREMENT.—Section 1834(a)(1)(E)(ii) of
8	such Act (42 U.S.C. 1395m(a)(1)(E)(ii)) is amended
9	by striking "1861(r)(1)" and inserting "1861(r)".
10	(3) Special rule in case of national mail-
11	ORDER COMPETITION FOR DIABETIC TESTING
12	STRIPS.—Section 1847(b) of such Act (42 U.S.C.
13	1395w-3(b)) is amended—
14	(A) by redesignating paragraph (10) as
15	paragraph (11); and
16	(B) by inserting after paragraph (9) the
17	following new paragraph:
18	"(10) Special rule in case of competition
19	FOR DIABETIC TESTING STRIPS.—
20	"(A) IN GENERAL.—With respect to the
21	competitive acquisition program for diabetic
22	testing strips conducted after the first round of
23	the competitive acquisition programs, if an enti-
24	ty does not demonstrate to the Secretary that
25	its bid covers types of diabetic testing strip

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products that, in the aggregate and taking into account volume for the different products, cover 50 percent (or such higher percentage as the Secretary may specify) of all such types of products, the Secretary shall reject such bid. The volume for such types of products may be determined in accordance with such data (which may be market based data) as the Secretary recognizes.

"(B) STUDY OF TYPES OF TESTING STRIP PRODUCTS.—Before 2011, the Inspector General of the Department of Health and Human Services shall conduct a study to determine the types of diabetic testing strip products by volume that could be used to make determinations pursuant to subparagraph (A) for the first competition under the competitive acquisition program described in such subparagraph and submit to the Secretary a report on the results of the study. The Inspector General shall also conduct such a study and submit such a report before the Secretary conducts a subsequent competitive acquisition program described in subparagraph (A)."

1	(4) Other conforming amendments.—Sec-
2	tion 1847(b)(11) of such Act, as redesignated by
3	paragraph (3), is amended—
4	(A) in subparagraph (C), by inserting "and
5	the identification of areas under subsection
6	(a)(1)(D)(iii)" after "(a)(1)(A)";
7	(B) in subparagraph (D), by inserting
8	"and implementation of subsection $(a)(1)(D)$ "
9	after ''(a)(1)(B)";
10	(C) in subparagraph (E), by striking "or"
11	at the end;
12	(D) in subparagraph (F), by striking the
13	period at the end and inserting "; or"; and
14	(E) by adding at the end the following new
15	subparagraph:
16	"(G) the implementation of the special rule
17	described in paragraph (10).".
18	(5) Funding for implementation.—In addi-
19	tion to funds otherwise available, for purposes of im-
20	plementing the provisions of, and amendments made
21	by, this section, other than the amendment made by
22	subsection $(e)(1)$ and other than section
23	1847(a)(1)(E) of the Social Security Act, the Sec-
24	retary of Health and Human Services shall provide
25	for the transfer from the Federal Supplementary

1	Medical Insurance Trust Fund established under
2	section 1841 of the Social Security Act (42 U.S.C.
3	1395t) to the Centers for Medicare & Medicaid Serv-
4	ices Program Management Account of \$20,000,000
5	for fiscal year 2008, and \$25,000,000 for each of
6	fiscal years 2009 through 2012. Amounts trans-
7	ferred under this paragraph for a fiscal year shall be
8	available until expended.

9 (e) Effective Date.—The amendments made by 10 this section shall take effect as of June 30, 2008.

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